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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/066,432	01/31/2002	Thomas F. Smith	07039-246001	5103

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EXAMINER

HORLICK, KENNETH R

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 02/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/066,432

Applicant(s)

SMITH ET AL.

Examiner

Kenneth R Horlick

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) 34-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27, 30-33 and 45-53 is/are rejected.
- 7) ☐ Claim(s) 28 and 29 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. (3 pages) 6) ☐ Other: _____

1. The specification is objected to because of the following informality: it contains active internet links. These must be deleted or modified so as not to be active.
2. Applicant's election without traverse of Group I, claims 1-33 and 45-53 in the paper filed 11/21/03 is acknowledged.
3. Claims 34-44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the paper filed 11/21/03.
4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
5. Claim 31 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim is confusing because "said portion" lacks proper antecedent basis. Correction is required.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-27 are rejected under 35 U.S.C. 102(a) as being anticipated by Espy et al. (J. Clin. Micro. Feb 2000).

Espy et al. clearly teach the claimed methods; see entire reference on pages 795-799. This is a reference to “others” as besides the four instant inventors, Espy et al. names three other authors.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5-27, and 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greenberg et al. (US 5,846,706) in view of Wittwer et al. (US 6,140,054).

These claims are drawn to methods comprising detection of HSV by PCR amplification of polymerase or TK nucleic acid sequences, and detection using two FRET-labeled oligonucleotide probes which hybridize adjacently on the amplified target nucleic acid.

Greenberg et al. disclose the detection of HSV using PCR and hybridization detection probes. The primers and probes target both the polymerase and TK genes, as required in the claims. This patent further discloses probes capable of distinguishing HSV-1 from HSV-2. See especially column 11, line 29 to column 12, line 38 and Example 2 in columns 13-14.

Greenberg et al. do not teach PCR combined with a detection system comprising two FRET-labeled oligonucleotide probes which hybridize adjacently on the amplified target nucleic acid.

Wittwer et al. disclose PCR combined with detection via two FRET-labeled oligonucleotide probes which hybridize adjacently on the amplified target nucleic acid, as well as melting temperature analysis to distinguish among variant target sequences (see column 2, lines 39-52; column 3, lines 19-40; column 4, lines 19-41; columns 11-19).

One of ordinary skill in the art would have been motivated to modify the HSV detection method of Greenberg et al. by using two FRET-labeled oligonucleotide probes

Art Unit: 1637

which hybridize adjacently on the amplified target nucleic acid because Wittwer et al. taught that such probe pairs provided an advantageous detection means. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed methods.

8. Claims 45-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greenberg et al. (US 5,846,706) in view of Livak et al.

These claims are drawn to methods comprising detection of HSV by PCR amplification of polymerase nucleic acid sequences, and detection using a probe comprising two labels enabling FRET detection.

Greenberg et al. disclose the detection of HSV using PCR and hybridization detection probes. The primers and probes target both the polymerase and TK genes, as required in the claims. This patent further discloses probes capable of distinguishing HSV-1 from HSV-2. See especially column 11, line 29 to column 12, line 38 and Example 2 in columns 13-14.

Greenberg et al. do not teach PCR combined with a detection system comprising a probe having two labels enabling FRET detection.

Livak et al. disclose PCR combined with detection via a probe having two labels enabling FRET detection (see especially Figure 1 on page 358).

One of ordinary skill in the art would have been motivated to modify the HSV detection method of Greenberg et al. by using a probe having two labels enabling FRET detection because Livak et al. taught that such a probe provided an advantageous

detection means. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed methods.

9. Claims 51-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greenberg et al. (US 5,846,706) in view of Higuchi et al.

These claims are drawn to methods comprising detection of HSV by PCR amplification of polymerase nucleic acid sequences, and detection using a nucleic acid binding dye.

Greenberg et al. disclose the detection of HSV using PCR and hybridization detection probes. The primers and probes target both the polymerase and TK genes, as required in the claims. This patent further discloses probes capable of distinguishing HSV-1 from HSV-2. See especially column 11, line 29 to column 12, line 38 and Example 2 in columns 13-14.

Greenberg et al. do not teach PCR combined with a detection system comprising a binding dye.

Higuchi et al. disclose PCR combined with detection via a binding dye (see pages 413-416).

One of ordinary skill in the art would have been motivated to modify the HSV detection method of Greenberg et al. by using a nucleic acid binding dye because Higuchi et al. taught that such a dye provided an advantageous detection means. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed methods.

Art Unit: 1637

10. Claims 28 and 29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. No prior art has been found teaching or suggesting HSV detection methods using the required primers or probes as set forth in the recited SEQ ID Nos.

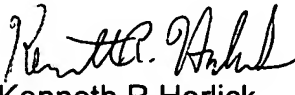
11. No claims are allowable.

12. Piiparinen et al., which teaches PCR methods of genotyping HSV-1 and HSV-2 targeting the polymerase gene, and Heller, which discloses an oligonucleotide which comprises the sequence of instant SEQ ID NO:10, are made of record as references of interest.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R Horlick whose telephone number is 571-272-0784. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782 The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Kenneth R Horlick, Ph.D.
Primary Examiner
Art Unit 1637

01/29/04